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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,119	11/18/1999	PHILIPPE SAUER	P63712US0	4763

7590

09/26/2002

JACOBSON PRICE HOLMAN & STERN  
400 SEVENTH STREET NW  
WASHINGTON, DC 20004

EXAMINER
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PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/26/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application N .

09/341,119

Applicant(s)

SAUER ET AL.

Examiner

Francisco C Prats

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 September 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 17 September 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 14-37.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

Francisco C Prats  
Primary Examiner  
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**ATTACHMENT TO ADVISORY ACTION**

The after-final amendment filed September 17, 2002, has been received. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

The after-final amendment filed September 17, 2002, will not be entered because it raises new issues for search and consideration. Specifically, the claims now require the use of a "bacterial crude lysate" as a starting material. This language clearly raises a new issue under 35 U.S.C. § 112, second paragraph. The language was previously rejected in the office action of February 14, 2001. Contrary to applicant's argument, it is not clear what purification steps are encompassed by the term "crude" and what purification steps are excluded. The specification does not clarify the issue. Simply put, the term "crude bacterial lysate" fails to describe, with precision, what product is contacted with the purification medium, and how that product is made. The claims simply do not recite any steps by which the bacterial cells are treated. The proposed new language therefore fails to put the practitioner on notice of what is encompassed by the claims and what is not. Because the amendment clearly raises a new issue for

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consideration, non-entry of the proposed amendment is proper under 37 CFR § 1.116.

Regarding the pending grounds of rejection, all of applicant's argument has been fully considered but is not persuasive of error. With respect to the issue of enablement, the specification invites the skilled artisan to experiment with critical process conditions, solvent and pH, to achieve a result which the specification itself demonstrates is uncertain, even with respect to embodiments specifically claimed. On the current record, applicant has not presented any evidence of the predictability of the claimed process, nor does the specification provide any guidelines as to which pH values encompassed by the claims will work, and which will not, and which chaotropic agents will work at which pH value. At best, the specification's few examples invite the practitioner to undertake a trial-and-error process with no guidance provided as to which combination of critical components will lead to success or failure within the broadly claimed parameters. The holding of non-enablement must be maintained.

With respect to the art rejection over Little and Marko, note specifically that, as discussed in previous office actions, these references provide disclosures of how to practice the claimed invention. To the extent that applicant urges

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inconsistency between the enablement rejection and the obviousness rejection, applicant's argument ignores the fact that the vast breadth of the present claim language encompasses both non-enabled embodiments as well as embodiments which the artisan of ordinary skill would consider obvious in view of the cited prior art. As to the motivation for varying the prior art process, note specifically that the prior art and the claims differ only infinitesimally, in that each of Little and Marko use a pH of 8 for their elution step, whereas the claims recite "a pH > 8". Thus, the artisan of ordinary skill clearly would have had a reasonable expectation that the claimed pH would have been suitable for use in the processes of Little and Marko, and would therefore have been motivated to have employed a pH greater than 8. As to the use of pre-treatment steps prior to DNA elution, note specifically that the after-final amendment has not been entered, so the processes of Marko and Little in fact use the same starting material as presently claimed -- a mixture having different nucleic acid species in addition to circular nucleic acids.

Moreover, even if the term "crude bacterial lysate" were present in the claims, applicant's argument would not be persuasive because the term "crude" can be properly construed to encompass the materials employed by Little and Marko. Because

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the proposed new language fails to state any process steps by which the starting material is made, and because the new language fails to exclude any pre-purification steps in a definite manner, the proposed new language does not distinguish the claims from the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP  
September 25, 2002